附件

关于药品信息化追溯体系建设的指导意见

（征求意见稿）

Text of the

China Guidance on the Construction of Drug Information and Traceability System

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Annex

Guidance on the Construction of Drug Information and Traceability System

(draft for comments)

In order to implement the "Opinions of the General Office of the State Council on Accelerating the Construction of Traceability System for Important Products" (Guo Ban Fa [2015] No. 95), the Ministry of Commerce and other departments, "Guiding Opinions on Promoting the Construction of Important Product Information Traceability System" (Business Rank) [2017] No. 53) and the "Opinions of the Food and Drug Administration on Promoting the Improvement of the Traceability System for Food and Drug Manufacturers" (Food and Drug Administration [2016] No. 122) and other documents stipulate that the drug information traceability system is now established. The following guidance is proposed.

I. Guiding ideology

In accordance with the decision-making and deployment of the Party Central Committee and the State Council, with the goal of safeguarding the safety of public drug use, we will accelerate the construction of a drug information traceability system and promote the transformation and upgrading of the pharmaceutical industry. Based on the implementation of the main responsibility of the enterprise, the company will establish a full-process drug information

traceability system in the direction of “one object, one code, traced together”, with the code and the trace as the direction, we will build a full-process drug information traceability system, improve the traceability standard of drug information, strengthen the sharing of traceability information, promote the comprehensive management of drug quality and safety, and improve the quality and safety of drugs.

II. The Work Target

The drug marketing license holder (including the pharmaceutical production enterprise holding the drug approval number, hereinafter referred to as the holder) and the business use unit establish a drug traceability system through informationization means to record and preserve the drug traceability information in a timely and accurate manner to form an interconnection. Interoperating with the drug traceability information data link, the source of the entire process of drug circulation can be investigated and traced; Effectively prevent counterfeit and inferior drugs from entering legal channels; ensure that drugs with quality and safety problems can be recalled and responsibilities can be investigated.

The drug production, circulation and use links together to build a drug traceability system covering the whole process. The quality management level of holders and drug management enterprises has been significantly improved, and the level of supervision and informationization and supervision efficiency of drug supervision and management departments have gradually increased, and industry associations have played an active role. The bridge of drug information and traceability system builds a leading role and leads the demonstration role. The public's awareness of drug information traceability is steadily improved, and drug information traceability information can be independently verified.

III. The Basic Principles

To establish a drug information traceability system, the following basic principles should be followed:

(1) The holder and the drug business use unit are responsible for each other. The holder and the drug business use unit are responsible for the quality and safety of the drug and have a retroactive obligation. The holder bears the main responsibility for the construction of the drug traceability system. The operating enterprise and the user unit actively cooperate with the holders to build a complete drug traceability system and fulfill their respective retroactive responsibilities.

(2) Department supervision and guidance. The drug supervision and administration department shall, in accordance with relevant laws and technical standards, supervise holders and drug business use units to establish a drug traceability system to guide industry associations to play an active role in the construction of [the] drug information traceability system.

(3) Classification is implemented step by step. Fully consider the number and management level of the holders, the pharmaceutical business units, as well as the actual development of the industry, adhere to the principles of enterprise establishment, and gradually advance in an orderly manner.

(4) All parties shall coordinate and [cooperate]. In accordance with the principle of territorial management, under the unified leadership of local governments, drug regulatory authorities should focus on coordinating and cooperating with the departments of work, business, health, and medical insurance to promote coordinated management and resource sharing of [the] drug information traceability systems.

IV. The Scope of Application

This guidance applies to the holders, pharmaceutical operating units to establish drug traceability systems and drug supervision and management departments of supervision and inspection. This guidance does not apply to the production and operation of Chinese herbal medicines, Chinese herbal medicines, raw materials and special packaging preparations.

V. Work Tasks

(1) Preparing unified informational traceability standards. In conjunction with the actual needs of the construction of [the] drug information traceability system, the State Drug Administration plans to establish a drug informationization traceability standard system, clarify the basic requirements, publish guidelines for the construction of [the] traceability system (Annex 1), unified drug traceability coding requirements (Annex 2), data and exchange standards.

(2) Enterprise construction information drug traceability system. Holders and pharmaceutical companies must abide by relevant laws and technical standards, establish and improve an information-based traceability management system, and earnestly perform the main responsibility. Holders and pharmaceutical companies shall record relevant activities in accordance with the requirements of quality management regulations. Records shall be true, accurate, complete, tamper-proof and traceable, and shall provide relevant data to the regulatory authorities in accordance with regulatory requirements; The system realizes traceability information storage, exchange, interconnection and intercommunication, and provides information inquiry for the public. Holders can build their own drug traceability systems or use third-party technology agencies. The drug business use unit cooperates with the holder's construction traceability system and uploads the corresponding traceability information to the traceability system.

The holder shall perform the responsibility for the traceability management of drug information, and shall assign a unique traceability mark to the sales packaging units at all levels of the product in accordance with the coding requirements proposed by the drug regulatory authority to achieve informational traceability. When selling drugs, the holder should provide relevant traceability information to downstream enterprises or medical institutions so that downstream companies or medical institutions can verify feedback. Holders must be able to obtain timely and accurate information on the entire process of circulation and use of the drugs produced.

When purchasing pharmaceuticals, pharmaceutical wholesale enterprises should obtain relevant traceability information from upstream enterprises and check them at the time of

drug acceptance; when selling drugs, they should provide relevant traceability information to downstream enterprises or medical institutions.

When purchasing drugs, the drug retail and use unit should obtain relevant traceability information from the upstream enterprise and check it at the time of drug acceptance; when selling the drug, the sales record details should be kept and the corresponding status mark of the sold drug should be adjusted in time.

Encourage information technology enterprises as third-party technical institutions to provide drug traceability information services for holders, pharmaceutical companies and users.

(3) Promoting the interconnection and interoperability of information. The State Drug Administration has established a nationwide drug traceability collaborative service platform to continuously improve the data exchange and sharing mechanism for drug traceability information. Encourage holders, pharmaceutical companies, users, industry associations, third-party service agencies, and administrative departments to implement drug traceability and collaborative service platforms to realize the interconnection and interoperability of drug information. Encourage enterprises to innovate inquiries and provide drug traceability information inquiry services to the public.

(4) Expanding the value of drug traceability information. The drug supervision and administration departments at all levels build a big data supervision system based on the drug information and traceability system, innovate drug quality supervision methods, explore the implementation of information technology and intelligent supervision of the whole process of drugs, and improve the risk early warning mechanism. Give full play to the role of drug traceability information in the work of problem product recall and emergency response mechanism, and further explore the application value of drug traceability information in supervision and inspection, product sampling inspection and daily supervision.

The ownership of the drug traceability data is “who generates and who owns”. The operator of the drug information traceability system may not disclose traceability information to third parties without authorization from all parties. Encourage third parties to use the traceability data of drugs to serve the society in a compliant and reasonable manner. Encourage industry associations and holders, pharmaceutical companies to explore the drug traceability data market trading mechanism, and establish a long-term mechanism for drug traceability marketization.

(5) Establish a data security mechanism. Drug traceability should ensure that drug traceability information is properly kept, and the duties of personnel are clearly identified to prevent problems such as information damage and loss. Traceability system operators should ensure the privacy and security of system user data. The drug traceability information record and

voucher retention period shall not be less than five years after the drug expires. The information collected by the drug traceability system shall be technically and institutionally guaranteed not to be tampered with. In order to ensure the authenticity, accuracy, completeness and traceability of the traceability information of the drug, the holder and the drug business enterprise should select a third-party organization for backup and ensure that the backup information is consistent with the original information.

(6) The drug supervision and administration department shall guide and supervise the construction of the traceability system. The drug regulatory authority shall perform its guiding and supervisory responsibilities and collect the required data according to regulatory requirements. The provincial drug supervision and administration department shall, in accordance with the relevant laws, regulations and standards, and these regulations, in combination with the actual conditions of the administrative region, formulate specific measures to clarify responsibilities at all levels.

The local drug supervision and administration department shall strengthen the supervision and inspection of the establishment of information and traceability systems for holders and drug business units, and urge relevant units to strictly abide by the traceability management system and establish a sound traceability system. For the failure to establish a traceability system as required, and the traceability system cannot operate effectively, it must be dealt with seriously in accordance with relevant laws and regulations.

VI. The Relevant Requirements

(1) Clearly focus and implement step by step. All provinces (autonomous regions and municipalities) can formulate implementation plans in light of regulatory actualities, and promote the construction of drug information and traceability systems step by step according to drug dosage forms and categories. Key products and key enterprises should be the first to be included in the traceability system, and priority should be given to the traceability system for products such as essential drugs and medical insurance reimbursement drugs that are of general concern to consumers. At the end of 2022, the complete coverage of the drug information and traceability system was basically completed.

(2) Strengthening guidance and social co-governance. It is necessary to give play to the self-discipline and model leadership of the industry, explore the establishment of the industry's own development planning and credit management system for the establishment of the drug information traceability system; carry out various forms of [pilot] activities around the key difficulties and weak links in the construction of the traceability system; To mobilize the polarity of the parties. It is necessary to strengthen the policy guidance of local regulatory authorities, urge enterprises to implement the main responsibility, actively promote the construction of information traceability system in the production and operation of pharmaceuticals, and timely dock the national credit system. It is necessary to strengthen the positive publicity of public opinion, play the role of the media, cultivate the public's awareness of drug traceability, and strive to form a good working atmosphere for

everyone's participation.

(Note: The drug information and traceability system is a traceability system related to drug quality and safety, such as drug listing license holders, operating enterprises, users, drug regulatory authorities, consumers, etc., through information technology, for drug production and circulation. The organic whole of tracking and traceability is used for information such as the use of various links. The drug traceability collaborative service platform is an information service platform for realizing the interconnection and interoperability of drug traceability systems. It can provide access address resolution of different traceability systems, and the filing of drug traceability code coding rules. Management, as well as services such as drug and enterprise basic data distribution.)

Attachments:

1. Guidelines for the construction of drug information and traceability system
2. Drug traceability code coding requirements
